

***Remarks***

Claims 12-16 are pending in the application, with claim 12 being the independent claim. Claims 1-11 were previously cancelled.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

***I. Supplemental Information Disclosure Statement***

Applicants note that a First Supplemental Information Disclosure Statement is submitted accompanying the Amendment and Reply. Applicants respectfully request the Examiner initial and return a copy of Information Disclosure Statement Forms.

***II. Rejoinder of Claims 15 and 16***

Claim 15 depends from claim 12 and further limits the insecticidally active compound of group 2 to pirimicarb. Applicants elected flonicamid, a species of insecticidally active compound of group 2 in the generic claim 12, for prosecution. Pirimicarb is one of two other insecticidally active compound of group 2 as recited in claim 12. As such, upon allowance of elected invention, Applicants respectfully request rejoinder of dependent claim 15 to the elected invention.

Claim 16 depends from claim 12, and is directed to a method of preparing the composition of claim 12. Section 1.475 (b)(3) of Title 37 of the Code of Federal Regulations states that a national stage application containing claims to a product, and a process specially adapted for the manufacture of said product will be considered to have

unity of invention. As such, upon allowance of elected invention (composition claims), Applicants respectfully request rejoinder of dependent claim 16 to the elected invention.

***III. Rejection under 35 U.S.C. § 103(a)***

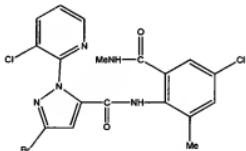
The rejection of claims 12-14 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Lahm *et al.*, Int'l Patent Appl. Pub. No. WO 03/015518 A1 (hereinafter "Lahm") is respectfully traversed.

***A. Prima facie Case of Obviousness Has Not Been Established***

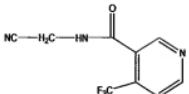
The examiner asserts that:

Lahm et al teach a method for controlling particular insect pests by applying their anthranilamide compounds. They also teach use of one or more other biologically active compounds or agents including insecticides, fungicides etc. including **flonicamid** (Page 96, lines 23-25 and 37).

The reference teaches anthranilamide derivative of following formula in their example 11 (Page 42, lines 18-20). . . .



Lahm et al disclose use of one or more other biologically active compounds or agents including insecticides, fungicides etc. including **flonicamid** (Page 96, lines 23-25 and 37) of the following structure in their composition containing anthranilamide derivatives [sic].



The reference teaches use of their compounds as a formulation or composition containing active ingredients 5-90 weight percent granules, tablets and powders. The reference does not specifically teach the ratio of individual active ingredient, it will be at least a ratio of 1:1 (Page 89, line 18) and this includes compound of group 2 and anthranilamide of formula II ratio from 500:1 to 1:50 as claimed by instant claim 13. The reference teaches suitable carrier comprising a solid diluent or surfactant (Page 89, lines 1-3). The reference thus teaches use of composition containing anthranilamide derivatives, insecticide and a surfactant.

\* \* \*

[I]t would have obvious to have selected various combinations of various disclosed ingredients (various insecticidal active compounds such as buprofezin, flonicamid and primicarb) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

(Office Action, pages 3-5.) Applicants respectfully disagree.

Lahm discloses compositions containing anthranilic acid amides and numerous mixing partners including, among numerous options, buprofezin, flonicamid or pirimicarb recited in the present claims. (Lahm, page 96, line 23, through page 97, line 33; and claim 8). However, Lahm does not provide any rationale for selecting components of the claimed composition. Moreover, Lahm recites laundry lists of potential mixing partners without any teaching of synergistic effects, or the mixing ratios as recited in the present claims.

The Examiner is of the opinion that Lahm teaches the mixing ratio of "at least a ratio of 1:1," citing page 89, line 18 of Lahm. Applicants respectfully disagree.

Page 89, lines 17 and 18 of Lahm reads: "The formulations will typically contain effective amounts of active ingredient, diluent and surfactant within the following approximate ranges that add up to 100 percent by weight." Nothing in this text, nor the text thereafter, teaches the mixing ratio of "at least a ratio of 1:1" as asserted by the Examiner.

In sum, there is nothing in Lahm that would have provided a reason for making the composition as recited in the present claims 12-14. Accordingly, the Examiner has not established a *prima facie* case obviousness of claims 12-14.

**B.      *The Evidence of Synergistic Effects Rebut Any Prima facie Case of Obviousness***

As discussed above, the Examiner has not established a *prima facie* case of obviousness of present claims 12-14. Moreover, Applicants submit herein a Declaration Under 37 C.F.R. § 1.132 by Dr. Wolfram Andersch ("the Declaration") to provide further evidence of synergistic effects obtained with presently claimed compositions. Synergistic effects have long been recognized as an indicator of non-obviousness. *See In Re Luvisi*, 144 U.S.P.Q. 646, 651-653 (CCPA 1965); *In re Lemkin*, 408 F.2d 1045, 1049 (CCPA,1969).

**(i)      *Method of Demonstrating Synergism***

The Board has recognized that there are many appropriate methods of demonstrating synergism. *See Ex parte Quadranti*, 25 U.S.P.Q.2d 1071, 1072-1073 (1992) ("There are undoubtedly many appropriate methods of demonstrating synergism. In each case, however, the facts shown must be analyzed to determine whether the method chosen in that case has in fact clearly and convincingly demonstrated the existence of synergism or, more generally speaking, an unobvious result.").

Synergism is shown where "the combined action of two or more agents . . . that is greater than the sum of the action of one of the agents used alone." *In Re Luvisi*, 144 U.S.P.Q. at 652.

Synergism of a given composition containing two or more active insecticidal compounds can be demonstrated by comparing the observed insecticidal activity of the composition to the calculated insecticidal activity according to the Colby formula. If the observed insecticidal activity is greater than that calculated, then the composition has a synergistic effect. Specifically, for a composition that contains two active insecticidal compounds, the calculated insecticidal activity is:

$$E = X + Y - \frac{X \bullet Y}{100}$$

wherein X denotes the efficacy when employing active compound A at an application rate of m g/ha or in a concentration of m ppm,<sup>1</sup> Y denotes the efficacy when employing active compound B at an application rate of n g/ha or in a concentration of n ppm, E denotes the efficacy when employing active compounds A and B at an application rate of m and n g/ha or in a concentration of m and n ppm. (Specification at page 41, lines 1-18.)

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<sup>1</sup> The units "g/ha" and "ppm" mean gram per hectare and parts per million, respectively.

***(ii) Synergistic Effects Demonstrated in the Declaration***

Applicants elected compound II-1-4, a species of anthranilamide of formula II, for prosecution. However, the Declaration include the data obtained from various combinations containing non-elected species of formula II. For the purpose of this reply, Applicants will discuss the data related to the combinations containing the elected species, *i.e.*, compound II-1-4, in detail below.

***(a) Aphis gossypii test***

In the study, cotton leaves that were infested by the cotton aphid (*Aphis gossypii*) were treated by being dipped into the preparations of tested compounds individually, or into a mixed preparation of the claimed composition. The efficacy of insect control was evaluated after 1 day. (The Declaration, Example A and Table A.)

As shown in Table A, when applied individually at 20 ppm of II-1-4 or 100 ppm of buprofezin, efficacies of 10% and 0% were observed for II-1-4 and buprofezin, respectively.<sup>2</sup> However, an efficacy of 40% was observed when the claimed composition (20 ppm II-1-4 + 100 ppm buprofezin, ratio 1:5) was applied. Thus, the efficacy (40%) of the claimed composition was ***much greater than*** the sum of the efficacy of II-1-4 and buprofezin applied individually (10% +0% = 10%). Therefore, the claimed composition has a synergistic effect in controlling *Aphis gossypii*, according to the definition of synergism in *In Re Luvisi*.

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<sup>2</sup> An efficacy of 0% indicates that none of the aphids were killed, and an efficacy of 100% indicates that all the aphids were killed.

Alternatively, according to Colby formula, the calculated efficacy of the claimed composition is 10%. However, the observed efficacy of the claimed composition was 40%, which is ***much greater than*** the calculated efficacy. Therefore, the claimed composition has a synergistic effect in controlling *Aphis gossypii*, according to Colby formula.

**(b) *Myzus persicae* test**

In the study, cabbage leaves that were infested by the green peach aphid (*Myzus persicae*) were treated by being sprayed with or dipped into the preparations of tested compounds individually, or with/into mixed preparations of the claimed compositions. The efficacy of insect control was evaluated after 1 day or 6 days. (The Declaration, Example B and Tables B1-B4.)

As shown in Table B2, when applied individually at 0.032 g/ha of II-1-4 or 0.8 g/ha of I-a-4, efficacies of 0% and 0% were observed for II-1-4 and I-a-4, respectively. However, an efficacy of 80% was observed when the claimed composition (0.032 g/ha II-1-4 + 0.8 g/ha I-a-4, ratio 1:25) was applied. Thus, the efficacy (80%) of the claimed composition was ***much greater than*** the sum of the efficacy of II-1-4 and I-a-4 applied individually (0% + 0% = 0%). Therefore, the claimed composition has a synergistic effect in controlling *Myzus persicae*, according to the definition of synergism in *In Re Luvisi*.

Alternatively, according to Colby formula, the calculated efficacy of the claimed composition is 0%. However, the observed efficacy of the claimed composition was 80%, which is ***much greater than*** the calculated efficacy. Therefore, the claimed composition has a synergistic effect in controlling *Myzus persicae*, according to Colby formula.

Similarly, as shown in Table B3, at the mixing ratio of 1:1, claimed compositions containing II-1-4 and flonicamid, or containing II-1-4 and I-a-4 have synergistic effects in controlling *Myzus persicae*, according Colby formula.

(c) *Phaedon cochleariae* larvae test

In the study, cabbage leaves were treated by being sprayed with or dipped into the preparations of tested compounds individually, or with/into mixed preparations of the claimed compositions. The cabbage leaves were then infested with larvae of the mustard beetle (*Phaedon cochleariae*), and the efficacy of insect control was evaluated after 2, 3 or 6 days. (The Declaration, Example C and Tables C1-C3.)

As shown in Table C3, when applied individually at 0.16 ppm of II-1-4 or 100 ppm of flonicamid, efficacies of 10% and 5% were observed for II-1-4 and flonicamid, respectively. However, an efficacy of 30% was observed when the claimed composition (0.16 ppm II-1-4 + 100 ppm flonicamid, ratio 1:625) was applied. Thus, the efficacy (30%) of the claimed composition was *much greater than* the sum of the efficacy of II-1-4 and flonicamid applied individually (10% +5% = 15%). Therefore, the claimed composition has a synergistic effect in controlling *Phaedon cochleariae*, according to the definition of synergism in *In Re Luvisi*.

Alternatively, according to Colby formula, the calculated efficacy of the claimed composition is 14.5%. However, the observed efficacy of the claimed composition was 30%, which is *much greater than* the calculated efficacy. Therefore, the claimed

composition has a synergistic effect in controlling *Phaedon cochleariae*, according to Colby formula.

*(d) Spodoptera frugiperda test*

In the study, cabbage leaves were treated by being sprayed with the preparations of tested compounds individually, or with a mixed preparation of the claimed composition. The cabbage leaves were then infested with larvae of the fall army worm (*Spodoptera frugiperda*). The efficacy of insect control was evaluated after 2 or 6 days. (The Declaration, Example D and Tables D1 and D2.)

As shown in Table D1, when applied individually at 0.16 g/ha of II-1-4 or 100 g/ha of flonicamid, efficacies of 17% and 0% were observed for II-1-4 and flonicamid, respectively. However, an efficacy of 50% was observed when the claimed composition (0.16 g/ha II-1-4 + 100 g/ha flonicamid, ratio 1:625) was applied. Thus, the efficacy (50%) of the claimed composition was ***much greater than*** the sum of the efficacy of II-1-4 and flonicamid applied individually ( $17\% + 0\% = 17\%$ ). Therefore, the claimed composition has a synergistic effect in controlling *Spodoptera frugiperda*, according to the definition of synergism in *In Re Luvisi*.

Alternatively, according to Colby formula, the calculated efficacy of the claimed composition is 17%. However, the observed efficacy of the claimed composition was 50%, which is ***much greater than*** the calculated efficacy. Therefore, the claimed composition has a synergistic effect in controlling *Spodoptera frugiperda*, according to Colby formula.

Similarly, as shown in Table D2, at the mixing ratios of 1:625, the claimed composition containing II-1-4 and pirimicarb has a synergistic effect in controlling *Spodoptera frugiperda*, according to the definition of synergism in *In Re Luvisi* and Colby formula.

*(e) Tetranychus urticae test*

In the study, bean plants that were infested with all stages of the two-spotted spider mite (*Tetranychus urticae*) were treated by being sprayed with the preparations of tested compounds individually, or with mixed preparations of the claimed compositions. The efficacy of insect control was evaluated after 6 days. (The Declaration, Example E and Table E.)

As shown in Table E, when applied individually at 4 g/ha of II-1-4 or 100 g/ha of I-a-4, efficacies of 0% and 80% were observed for II-1-4 and I-a-4, respectively. However, an efficacy of 95% was observed when the claimed composition (4 g/ha II-1-4 + 100 g/ha I-a-4, ratio 1:25) was applied. Thus, the efficacy (95%) of the claimed composition was ***much greater than*** the sum of the efficacy of II-1-4 and I-a-4 applied individually (0% + 80% = 80%). Therefore, the claimed composition has a synergistic effect in controlling *Tetranychus urticae*, according to the definition of synergism in *In Re Luvisi*.

Alternatively, according to Colby formula, the calculated efficacy of the claimed composition is 80%. However, the observed efficacy of the claimed composition was 95%, which is ***much greater*** than the calculated efficacy. Therefore, the claimed composition has a synergistic effect in controlling *Tetranychus urticae*, according to Colby formula.

In summary, Applicants have demonstrated synergistic effects of presently claimed compositions, at different mixing ratios, in controlling different insects, by more than one appropriate method. The evidence of synergistic effects rebuts the obviousness rejection of present claims 12-14, assuming a *prima facie* case of obviousness could have been established. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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